

substitute form PTO-1449

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**



Application Number	10/092880
Filing Date	March 8, 2002
First Named Inventor	Barenkamp
Group Art Unit	1645
Examiner Name	J. G. [signature]
Attorney Docket Number	5127

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U.S. PATENT DOCUMENTS					
Init.		Number	Patentee	Publ'n Date	Relevant Portion
[initials]	A	5194254	Barber et al.	Mar. 16, 1993	_____
	B	4855283	Lockhoff et al.	Aug. 8, 1989	_____
	C	4258029	Moloney et al.	Mar. 24, 1981	_____
[initials]	D	4952496	Studier et al.	Aug. 28, 1990	_____

FOREIGN PATENT DOCUMENTS						
OG ↓	E	WO	93/19090	Barenkamp	Sept.30,1998	_____
	F	WO	94/21290	Barenkamp	Sept.29,1994	_____
	G	WO	92/17167			

OTHER DOCUMENTS		
	H	Description
[initials]	I	Pediatric Infection Disease Journal, Vol. 9, No. 5, issued May 1990, S.J. Barenkamp et al., "Development of Serum Bactericidal Activity Following Nontypeable <i>Haemophilus influenzae</i> Acute Otitis Media", pgs. 333-339, see entire document
	J	Journal of clinical Microbiology, Vol. 29, No. 11, issued November 1991, A.C. Caputa et al., "110 Kilodalton Recombinant Protein which is Immunoreactive with Sera from Humans, Dogs, and Horses with Lyme Borrelia", pgs. 2418-2423, see entire documents.
[initials]	K	Joint Meeting of the American Pediatric Society for Pediatric Research, 07-10 May 1990, S.J. Barenkamp, "Cloning and Expression of Genes for Nontypeable <i>Haemophilus influenzae</i> (NTHI) High Molecular Weight (HMW) Outer Membrane Proteins which are Targets of Bactericidal Antibody", Abstract 983, Pediatric Research, Vol. 27, (4 part 2).

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L	The Journal of Infectious Diseases, Vol. 165 (Suppl.) Issued August 1992, S.J. Barenkamp, "Outer Membrane Protein and Lipopolysaccharides of Nontypeable Haemophilus influenzae", pgs. S181-S184, see entire document.
M	Infection and Immunity, Vol. 60(4), issued April 1992, S.J. Barenkamp et al, "Cloning, Expression and DNA Sequence Analysis of Genes Encoding Nontypeable Haemophilus influenzae High-Molecular-Weight Surface-Exposed Proteins Related to Filamentous Hemagglutinin of Bordetella pertussis pgs. 1302-1313, see entire document.
N	Infection and Immunity, Vol. 56(1), issued January 1988, E.J. Hansen, "Immune Enhancement of Pulmonary Clearance on Nontypeable Haemophilus influenzae, pgs. 182-190, see entire document, especially Figs. 3 and 4.
O	Infection and Immunity, Vol. 52(2), issued May 1986, S. J. Barenkamp, "Protection by Serum Antibodies in Experimental Nontypeable Haemophilus influenzae Otitis Media", pgs. 572-578, see Figs. 1 and 2.
P	Proceedings of the National Academy of Sciences USA, Vol. 80, issued March 1983, R.A. Young et al. "Efficient Isolation of Genes by Using Antibody Probes", pgs. 1194-1198, see entire document.
Q	Infection and Immunity, Vol. 45(3), issued September 1984, R. Schneerson et al, "Serum Antibody Responses of Juvenile and Infant Rhesus Monkeys Injected with Haemophilus influenzae Type b and Pneumococcus Type 6A Capsular Polysaccharide-Protein Conjugates", pgs. 582-591, see entire document.
R	Journal of Molecular Biology, Vol. 157 issued 1982, J. Kyte et al, "A Simple Method for Displaying the Hydropathic Character of Protein", pgs. 105-132, see entire document.
S	Proceedings of the National Academy of Sciences, Vol. 78(6), issued June 1981, T.P. Hopp et al, "Prediction of Protein Antigenic Determinants from Amino Acid Sequences", pgs. 3824-3828, see entire document.
T	Pediatr. Infect. Dis. J., 9: 333-339, 1990, Stephen J. Barenkamp and Frank F. Bodor, "Development of Serum Bacterial Activity Following Nontypeable Haemophilus influenzae Acute Otitis Media"
U	Green et al, Infection and Immunity 61:1950-1957, 1993

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V	Erwin et al, Can. Journ. Of Microbiology 34:, 723-729, 1988	
W	Thomas et al, Infection and Immunity, 58: 1909-1913, 1990	
X	Barenkamp, Pediatric Research Vol. 29, 167A, Abstract 985, 1991	
Y	Barenkamp, Abstract 983, Pediatric Research Vol. 27	
Z	Houghten et al, Vaccine 86, pgs. 21 to 25	
a	Gulig et al, Dissertation Abstract Internat, 1985, Vol. 46/08 B. page 2613	
b	Barenkamp et al, Pediatric Research 31:179A, 1992	
c	Kimura et al, Infection and Immunity 27:253-9, 1985	
d	Barenkamp et al, Abstracts of the Fifth International Symposium Advances in Otitis Media Abstract 133, page 119, 1999	
e	Green et al, Abstract, Infect Immun 1991 Sept; 59(9) 3191-8	
f	Spinola et al, Abstract, Infect Immun 1992 Feb; 60(2) 385-91	
g	Nixon-George et al., The Adjuvant Effect of Stearyl Tyrosine on a Recombinant Subunit Hepatitis B Surface Antigen, J. Immunol. Vol. 144: pp. 4798-4802; June 15, 1990	
h	Weismuller K-H et al., Novel low molecular weight synthetic vaccine against foot-and-mouth disease containing a potent B-cell and macrophage activator, Vaccine Vol.7, pp. 29-33, Feb.1989	
i	Chang et al., Nature 275, pp. 617-624, 1978	
j	Itakura et al., Science 198, pp. 1056-1063, 1977	
k	Goeddel et al., Nature 281, pp. 544-548, 1979	
l	Goeddel et al., Nucl. Acids Res. 8, pp. 4057-4074, 1980	
m	Shakin R.D. et al., Mucosal Immunization with filamentous hemagglutinin protects against Bordetella pertussis respiratory infection. Infect. Immun. 60, pp. 1482-1488, 1992	

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OTHER DOCUMENTS		
n		Giebink G.S. et al., Pneumococcal Capsular Polysaccharide- meningococcal outer membrane protein complex conjugate vaccines: Immunogenicity and efficacy in experiment pneumococcal otitis media. J. Infect. Dis 167, pp. 347-355, 1993
o		Selected Abstracts from 1993 Interscience Conference on Antimicrobial Agents and Chemotherapy (Annual American Society for Microbiology ICAAC Meeting) in New Orleans
p		Green B. A. et al., Evaluation of mixtures of purified Haemophilus Influenzae outer membrane proteins in the chinchilla otitis media model. Infect. Immun. 61, pp. 1950-1957, 1993
q		Murphy T. F. et al., Somatic Antigens of Haemophilus Influenzae as vaccine components. Pedia Infect. Dis. J. 8, pp. S66-S68, 1989
r		Consensus. Pediatr. Infect. Dis. J. 8, pp. S94-S97, 1989
s		Makela et al., Pneumococcal Vaccine and Otitis Media, Lancet 2, pp. 547-551, 1990
t		Giebink et al., J. Infect. Dis. 140, pp. 716-723, 1979
u		Giebink, Rev. Infect. Dis. 3, pp. 342-352, 1981
v		Van Regenmortel, M.H.V., Immunology Today 10(8), pp. 266-272, 1989
w		Dick, W.E. et al., Microbiol. Immunol. 10, pp. 48-114, 1989
x		Roitt, I.M. et al., Immunology, C.V. Mosby Co. St. Louis, Gower Medical Publishing, London, 1989, pp. 8.3-8.4, 1985
y		Boslego, J.W. et al., Vaccine 9, pp. 154-162, March 1991
z		Beachey J. Infect. Dis. 143, pp. 325-345, 1981
AA		Barenkamp S. J., St. Geme JW III. Genes encoding high molecular weight adhesion proteins of nontypeable Haemophilus influenzae are part of gene clusters. Infect Immun 62, pp. 3320-3328, 1994
BB		Brunham, R.C., F.A. Plummer, and R.S. Stephens, 1993, Bacterial antigenic variation, host immune response, and pathogen-host coevolution. Infect. Immun. 61, pp. 2273-2276

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CC	Green B.A., T. Quinn-Dey, and G.W. Zlotnick. 1987, Biologic activities of antibody to peptidoglycan-associated lipoprotein of Haemophilus influenzae against multiple clinical isolates of H. influenzae type b. Infect. Immun 55, pp. 2878-2883
DD	Green B.A., B.J. Metcalf, T. Quinn-Dey, D.H. Kirkley, S.A. Quataert, and R.A. Deich, 1990. A recombinant non-fatty acylated form of the Hi-PAL (P6) protein of Haemophilus influenzae elicits biologically active antibody against both nontypeable and type b H. influenzae. Infect. Immun. 58, pp. 3272-3278
EE	Gnehn, H.E., S.I. Pelton, S. Galati, and P.A. Rice, 1985. Characterization of antigens from nontypeable Haemophilus influenzae recognized by human bactericidal antibodies: Role of Haemophilus outer membrane proteins. J. Clin. Invest 75, pp. 1645-1658.
FF	Groeneveld, K., L. van Alphen, C. Voorter, P.P. Eijk, H.M. Jansen, and H.C. Zanen. 1989. Antigenic drift of Haemophilus influenzae in patients with chronic obstructive pulmonary disease. Infect. Immunol. 57, pp. 3038-3044
GG	Groeneveld, K., L. van Alphen, P.O. Eijk, H.M. Jansen, and H.C. Zanen. 1988. Changes in outer membrane proteins of nontypeable Haemophilus influenzae in patients with chronic obstructive pulmonary disease. J. Infect. Dis. 158, pp. 360-365
HH	Goding, J.W., 1986. Monoclonal antibodies: Principles and practice, pp. 59-141. Academic Press Limited, London
II	Hansen, E.J. D.A. Hart, J.L. McGehee, and G.B. Toews, 1988. Immune enhancement of pulmonary clearance of nontypeable Haemophilus influenzae. Infect. Immun. 56, pp. 182-190
JJ	Karasic, R.B., C.E. Trumpp, H. Gnehn, P.A. Rice and S.I. Pelton, 1985. Modification of otitis media in chinchillas rechallenged with nontypeable Haemophilus influenzae and serologic response to outer membrane antigens. J. Infect. Dis. 151, pp. 273-279
KK	Kilian, M., 1985. Haemophilus, pp. 387-393. In E.H. Lennette, A. Balows, W.J. Hausler, Jr., and H.J. Shadowmy (ed.), Manual of clinical microbiology, 4th ed. American society for Microbiology, Washington, D.C.
LL	Kuklinska, D. and M. Kilian, 1984. Relative proportions of Haemophilus species in the throat of healthy children and adults. Eur. J. Clin. Microbiol. 3, pp. 249-252

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MM		Murphy, T.F., L.C. Bartos, P.A. Rice, M.B. Nelson, K.C. Dudas, and M.A. Apicelia, 1986. Identification of a 16,600 dalton outer membrane protein of nontypable Haemophilus influenzae as a target for human serum bactericidal antibody. J. Clin. Invest. 78, pp. 1020-1027
NN		Murphy, T.F. and M.A. Apicelia, 1987. Nontypable haemophilus influenzae: A review of clinical aspects, surface antigens and the human immune response to infection. Rev. Infect. Dis. 9, pp. 1-15
OO		Murphy, T.F. and L.C. Bartos, 1988. Purification and analysis with monoclonal antibodies of P2, the major outer membrane protein of nontypable Haemophilus influenzae. Infect. Immun. 56, pp. 1084-1089
PP		Murphy, T.F. and L.C. Bartos, 1988. Human bactericidal antibody response to outer membrane protein P2 of nontypable haemophilus influenzae. Infect. Immun. 56, pp. 2673-2679
QQ		Rabinovich, N.R., P. McInnes, D.L. Klein, and B.f. Hall, 1994. Vaccine technologies: view to the future. Science 265, pp. 1401-1404
RR		St. Geme, J.W. III., S. Falkow, and S.J. Barenkamp, 1993. High-molecular-weight proteins of nontypable Haemophilus influenzae mediate attachment to human epithelial cells. Proc. Natl. Acad. Sci. USA 90, pp. 2875-2879
SS		Tabor, S., and C.C. Richardson, 1985. A bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes. Proc. Natl. Acad. Sci. USA 82, pp. 1074-1078
TT		Wallace, R.J., jr. D.M. Musher, E.J. Septimus, J.E. McGowan, Jr., F.J. Quinones, K. Wiss, P.H. Vance, and P.A. Trier, 1981. Haemophilus influenzae infection in adults: characterization of strains by serotypes, biotypes, and beta-lactamase production. J. Infect. Dis. 144, pp. 101-106
UU		Yamanaka, N. and H. Faden, 1993. Antibody response to outer membrane proteins of nontypable Haemophilus influenzae in otitis-prone children. J. Pediatr. 122, pp. 212-218
VV		Abstracts of the 31 st Inter science conference on Antimicrobial Agents and Chemotherapy, vol. 31, October 1991, p. 286, S.J. Barenkamp, Abstract No. 1126

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J. Fraser

Date Considered

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